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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,325	09/05/2007	Ulf Houlberg	58982.000040	1838
21967	7590	02/02/2010	EXAMINER	
HUNTON & WILLIAMS LLP			MUI, CHRISTINE T	
INTELLECTUAL PROPERTY DEPARTMENT				
1900 K STREET, N.W.			ART UNIT	PAPER NUMBER
SUITE 1200				1797
WASHINGTON, DC 20006-1109				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,325	HOULBERG ET AL.	
	Examiner	Art Unit	
	CHRISTINE T. MUI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 July 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-41 and 43-52 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-41 and 43-52 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 14 July 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>14 July 2006; 02 November 2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
2. This is specifically on page 5, line 26.
Appropriate correction is required.
3. The use of the trademark INTEL has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.
Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

This is specifically on page 14, line 34.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “318, page 16, line 9” has been used to designate both saving procedure and display procedure. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being

amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 316. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 8-35, 37, 39-41 and 43-52 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 301 699 A2 to Richardson (submitted on the Information Disclosure Statement on 14 July 2006; herein referred 'Richardson').

3. Regarding claims 1-6, 8-35, 37 and 43-52, the reference Richardson discloses a method for determining the bioactivity of liquid biological mixtures or samples, including solutions, emulsions, suspensions and solids. Once the sample is obtained it is placed in a microtiter well with an upper surface, visual spectrum light is directed into the liquid biological mixture and reflectance of the light from the mixture is detected and quantified. The visual light can be from a strobe flash occurring at regular intervals for adequate readings of reflected color. The apparatus incorporated a microcolorimeter with high energy source as a reflectance detector. The detector can be fitted with an appropriate incubator environment which would have controlled robotic devices to receive, identify and position plates appropriate, reading and for discard. Data is collected and compared by computer and the computer calculates the desired information on bioactivity for each individual well in the microtiter plate. The detector produces 'tristimulus' color values to breakdown the reflected visual spectrum light into how light or dark a sample is, the measure change between red and green and measure changes between blue to yellow. The color image by the three different dimensions is considered to be the image file of the sample being reacted. The analysis include determination of the three dimensions of the tristimulus color values so that extremely fine differences in color can be detected and a computer system is used

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such as an IBM compatible microcomputer with adequate storage such as the 30 MB hard disc containing Telecat of Televideo Co. It can be seen in Figure 3, the microcolorimeter disposed at a desired position to determine the tristimulus color values is connected to a color analyzer, which is also connected to a computer for display, storage, reading and discard. It is interpreted by the examiner that since the microcolorimeter is disposed on the underside of the microwell, it is interpreted that the well is at least partly transparent on a surface. Further, traditional dyes can be used for microbiological research and testing such as litmus, methylene blue and resazurin as well as brom cresol purple, brom thymol blue, TTC and CVT. The dyes can change color based on pH or O/R or both.

4. Richardson further discloses the term biological mixtures refer to mixture such as dairy products and other related types of food products, pharmaceuticals, blood, environmental samples and cosmetics. Some products that may be used are milk and yogurt. Bioactivity refers to the pH, conductivity and other characteristics influenced by microorganism content, cell function and other biological parameters. Examples of tests of bioactivity in the dairy industry is for testing include abnormal milk; antibiotics; total bacterial count; coliforms; laboratory pasteurized samples; bacterial spores; psychrotrophs; product shelf life stability; sterility; staphylococci; other pathogens; lactic culture activity; bacteriophage test; yeast in yogurt; cheese contaminants; DNASE activity; lipase and proteolytic activities. It can be seen in Figure 4, Richardson discloses the microtiter well is part of a microtiter plate 52, with at least 2 wells. Richardson also discloses and teaches the regularly spaced light pulses that are

directed into the biological system and the reflectance continuously measured in turn can be in flashes that occur 1 to seconds apart so that samples are rapidly detected.

The measurement step of measuring the casein suspension as they become clear with proteolysis or fat emulsions as they lose turbidity with lipolysis is considered to be measuring viscosity, or in other words, loss of turbidity of the sample (see abstract, column 6, line 50-column 7, line 15, column 7, line 32-column 8, line 45, column 11, line 3-column 14, line 35, claims 1-22).

5. Regarding claims 39-41, the reference Richardson disclose an apparatus for determining the bioactivity of liquid biological mixtures. The apparatus can be seen in Figures 1-4 in different embodiments. The apparatus, in general, comprises a microtiter well plate to contain the biological mixture; a dye, of fine color changes that is to be detected and is correlated to changes in bioactivity of the sample; an incubator environment; a detector for collecting and comparing by computer for calculating desired information on bioactivity. The detector produces 'tristimulus' color values to breakdown the reflected visual spectrum light into how light or dark a sample is, the measure change between red and green and measure changes between blue to yellow. The color image by the three different dimensions is considered to be the image file of the sample being reacted. The computer disclosed is considered to be the analyzer for analyzing the different dimensions. Richardson further discloses and teaches the traditional dye can be litmus, methylene blue and resazurin as well as brom cresol purple, brom thymol blue, TTC and CVT. The dyes can change color based on pH or O/R or both. Richardson further discloses and teaches the apparatus may be used in

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addition to determining the bioactivity of the mixture, but also to measure, for example, the casein suspension as they become clear with proteolysis or fat emulsions as they lose turbidity with lipolysis (see abstract, Figures 1-4, column 6, line 51-column 7, line 15, column 7, line 32-42, column 8, line 20-27, column 11, line 3-8, column 11, line 32-column 38, column 13, line 30-column 14, line 35). The measurement step of measuring the casein suspension as they become clear with proteolysis or fat emulsions as they lose turbidity with lipolysis is considered to be measuring viscosity, or in other words, loss of turbidity of the sample.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson as applied to claim 1 above, and further in view of US Publication No. 2001/0039032 to Matsumura (submitted on the Information Disclosure Statement on 14 July 2006; herein referred ‘Matsumura’).

10. Regarding claim 7, the reference Richardson discloses the claimed invention except for where the scanning device is a camera. Matsumura discloses disposable plates in which microorganisms are detected and/or scanned as well as determining the susceptibility of microorganisms to various antibiotics and/or identifying microorganisms. The instrument employs image acquisition technology, several image processing algorithms, and a variety of specialized disposable plates to perform these functions. CCD linear array scanner, a CCD line-scan camera, a CCD 2D array camera (still or motion video), a laser scanning camera, or other device that would provide a sufficiently clear image of the plate that can be used alone or after further processing. The instrument performs three main functions on the sensor plate: plate incubation, image acquisition/capture, and image processing (see abstract, [0015, 0060-0061]).

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11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the scanning device to be a digital camera for faster processing of captured images as well as obtaining a sufficiently clear image of the container to distinguish the three different dimensions of the tristimulus color values.

12. Claims 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson.

13. Regarding claims 36 and 38, the reference Richardson discloses the claimed invention except for where the color indicator is either brilliant blue or Ruthenium Red. Richardson disclose traditional dyes may be added to sample such as litmus, methylene blue and resazurin as well as brom cresol purple, brom thymol blue, TTC and CVT (see abstract, column 11, line 48-column 12, line 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the color indicator to be either brilliant blue or Ruthenium Red when binding to dairy products, such as yogurt, so there is a vivid color change when the viscosity of the medium changes as well as having color indicators the tightly bind to the medium so that there is no separation between the indicator and medium or to use indicators that inhibit intracellular calcium receptors in a dairy medium .

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797